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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,810	11/19/2003	Michael R.S. Hill	P-9092-04	7000
27581	7590	03/15/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			LAYNO, CARL HERNANDZ	
			ART UNIT	PAPER NUMBER
			3766	
DATE MAILED: 03/15/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

E

Office Action Summary

Application No.

10/716,810

Applicant(s)

HILL ET AL.

Examiner

Carl H. Layno

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-16, 19-30 and 34-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-16, 19-25, 34 and 35 is/are allowed.
- 6) ☒ Claim(s) 26-28, 36-38 and 40-45 is/are rejected.
- 7) ☒ Claim(s) 29, 30, 39 and 46-49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgment is made of applicant's amendment, which was received by the Office on January 17, 2006.

2. Claims 1, 2, 17, 18, and 31-33 have been canceled. Claims 3-16, 19-30, and 34-49 are active.

Claim Rejections - 35 USC § 102/103

3. In view of applicant's claim cancellations, the Examiner is withdrawing the 35 U.S.C 102(b)/103(a) rejections based upon the Mackey '877 and Elsberry et al '689 patents, which were made against claims 1, 2, 17, 18, and 31-33 in the last Office action.

4. However, upon further consideration, a new ground(s) of rejection is made in view of the Hartlaub (US 6,134,470) and Cammilli et al (US 6,167,305) patents.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 26-28, 36-38, and 40-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartlaub (US 6,134,470).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In regard to claim 26, the Hartlaub (US 6,134,470) patent describes an apparatus for treating a tachyarrhythmic patient (Figs. 1 and 2) using electrical stimulation. The device (Fig.2) comprises a microprocessor 224, spinal cord stimulation electrodes (330,332,334,336), and cardiac stimulation electrodes (317,321,324,326,310,311,320,318). In use, the spinal cord stimulation is activated in response to a detected arrhythmia. The device then senses whether or not the arrhythmia has been terminated. If not, anti-tachycardia pacing therapy may be delivered (col.12, lines 3-8).

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In regard to claim 27, the spinal cord stimulation electrodes are considered to be “metal” and are quadripolar in-line assemblies in Medtronic™ Model 3487A or 3888 leads (col.4, lines 41-50).

In regard to claim 28, the cardiac leads appear to be defibrillation leads with cardiac pacing electrodes (Figs.1 and 2), among them a “screw-in” electrode **166** (Fig.1) and bipolar electrodes (**317,321,324,326** – Fig.2).

In regard to claim 36, the device could conceivably use spinal cord stimulation (SCS) in combination with pacing (or defibrillation) therapy to treat an arrhythmia (col.12, lines 3-8). The spinal cord stimulation treatment would stop when the device senses that tachyarrhythmia is no longer present and a normal sinus rhythm (NSR) has begun (Fig.4 – block **422**).

In regard to claims 37, 38, and 40, the Hartlaub stimulator may be equipped with an implantable drug pump (Abstract, lines 20-22 and col.5, lines 3-13) for delivering “anti-tachyarrhythmia drugs”. These drugs would, in all likelihood, be produced synthetically (i.e. manufactured).

In regard to claim 41, the spinal cord stimulation lead **124** is placed in the intrathecal or epidural space (Fig.3). See col.4, lines 44-46.

In regard to claim 42, the spinal cord stimulator may be employed for treating chronic pain (col.13, lines 15-23).

In regard to claims 43 and 44, depending upon the presence or absence of tachyarrhythmias, cardiac and nerve stimulation will be active; hence, intermittent operation.

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7. Claims 36, 37, 42, and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Cammilli et al (US 6,167,305).

The Cammilli et al (US 6,167,305) patent describes an implantable defibrillation system (Fig.1), which uses a spinal cord nerve stimulator C as an analgesic prior to and during stimulation by a shock generator E (Abstract).

In regard to claims 37 and 42, the device may, alternatively, be equipped with a drug infusion pump for administering an analgesic (col.4, lines 15-21).

Allowable Subject Matter

8. Claims 29, 30, 39, and 46-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 3-16, 19-25, 34, and 35 are allowed.

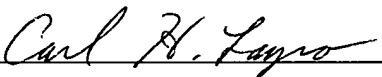
Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CARL LAYNO
PRIMARY EXAMINER

CHL
3/10/2006